

**510(k) SUMMARY**

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**OTOTECH INTERNATIONAL  
MODEL ALPHA BEHIND-THE-EAR  
HEARING INSTRUMENTS.**

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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Contact Person: Same as above

Date Prepared: 5/20/96

**Name of device and Name/Address of Sponsor**

Model Alpha Behind-The-Ear Hearing Instruments

Ototech International Inc.  
3400 N.W. 56  
Oklahoma City, Oklahoma 73112

**Classification Name**

The Model Alpha Behind-The-Ear Hearing Instrument is among those devices commonly referred to as air conduction hearing aids. The devices have been classified by the Ear, Nose and Throat Classification Panel as Class I devices set forth in 21 CFR 874.3300.

**Predicate Devices**

Starkey SM PC  
Starkey SM Vega  
Bosch Star 22

## **Proposed Labels, Labeling and Advertisements Sufficient to Describe the Device, its Intended Use and the Directions for its Use.**

Included in this submission are the proposed labeling for the Ototech International Model Alpha Behind-The-Ear Hearing Instrument. This includes the User Instruction Booklet (Appendix A), Label Specifications (Appendix B), Product Specification/Fitting Information (Appendix C), and Substantially Equivalent Devices (Appendix D).

### **Intended Use**

The Ototech International Model Alpha Behind-The-Ear Hearing Instrument is intended for use by individuals with **Moderate or Mild to Severe** hearing loss.

### **Product Description**

The Model Alpha is a linear hearing device. The electronics for this hearing instrument are contained in a custom acrylic plastic case. The device has one user control - the volume wheel, and no potentiometers. The device does not require any special fitting systems.

The acoustical output of the Ototech Model Alpha is a maximum SSPL90 of 122 dB SPL (ANSI S3.22, 1987). The reference test gain is 43 dB SPL.

### **Technological Characteristics and Substantial Equivalence**

#### **Ototech Alpha Behind-the-Ear Hearing Instrument Data according to ANSI S3.22-1987**

##### **1. Electrical and Acoustical Data**

SSPL90 maximum output	122 dBSPL
HF average SSPL90	121 dBSPL
HF average full-on gain	50 dBSPL
Reference test gain	43 dBSPL
Equivalent input noise	25 dBSPL
Frequency range	200-5800 Hz
T.H.D. at 500 Hz	5 %
T.H.D. at 800 Hz	5 %
T.H.D. at 1600 Hz	3 %
Battery Size	675
Battery Type	Zinc-air
Battery current drain	.9 mA
Typical battery life	600hrs

The three predicate devices listed above are also linear devices having similar maximum output ranging from 118 to 127dB SPL, and similar gain ranging from 33 to 45dB SPL. The Starkey SM Vega has no potentiometers. The Bosch Star 22 has a tone potentiometer. The Starkey SM PC has one output and one tone potentiometer.